

Appln. No. 09/716,356  
Amd. dated August 5, 2004  
Reply to Office Action of February 17, 2004

**Amendments to the Claims**

This listing of claims will replace all prior versions, and listings, of claims in the application:

**Listing of Claims:**

1(Original). A purified polypeptide, comprising an amino acid sequence selected from the group consisting of:

(a) SEQ ID NO:6; where amino acid residue 73, as represented by Xaa, is Ile or Thr;

(b) a contiguous fragment of SEQ ID NO:6, which fragment induces interferon- $\gamma$  production in immunocompetent human cells; and

(c) a variant of (a) or (b) differing therefrom by replacement of one amino acid residue, which variant induces interferon- $\gamma$  production in immunocompetent human cells.

2(Original). The purified polypeptide of claim 1, which has a molecular weight of about  $18,500 \pm 3,000$  daltons on sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE) and an isoelectric point of about  $4.9 \pm 1.0$  on chromatofocusing.

Claim 3 (Cancelled)

4(Original). The purified polypeptide of claim 1, which comprises the amino acid sequence of a contiguous fragment

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of SEQ ID NO:6, where amino acid residue 73, as represented by Xaa, is Ile or Thr, which fragment induces interferon- $\gamma$  production in immunocompetent human cells.

5(Original). The purified polypeptide of claim 1, which comprises a variant of (a) or (b) differing therefrom by replacement of one amino acid residue, which variant induces interferon- $\gamma$  production in immunocompetent cells.

6(Original). A pharmaceutical composition, comprising the polypeptide of claim 1 as an active ingredient and a pharmaceutically-acceptable carrier.

7(Original). The pharmaceutical composition of claim 6, further comprising interleukin 2.

8(Original). The pharmaceutical composition of claim 6, further comprising interleukin 12.

9(Original). The pharmaceutical composition of claim 6, further comprising interleukin 3.

Claims 10-17 (Cancelled)

18(Currently amended). A pharmaceutical composition, comprising:

(i) an interferon- $\gamma$  inducing polypeptide ~~which is~~  
selected from the group consisting of (a) a polypeptide of SEQ ID  
NO:6 obtainable from humans, where amino acid residue 73 of SEQ  
ID NO:6, as represented by Xaa, is Ile or Thr, ~~[[or]]~~ (b) a  
contiguous fragment thereof, or (c) a homologous polypeptide  
thereof, wherein the polypeptide of SEQ ID NO:6 and the  
homologous polypeptide thereof have the following  
physicochemical properties:

(1) an amino acid sequence selected from the group  
consisting of SEQ ID NO:6, where amino acid  
residue 73, as represented by Xaa, is Ile or Thr,  
and a homologous sequence thereof where at least  
one amino acid residue in SEQ ID NO:6 is replaced  
with a different amino acid, or at least one amino  
acid residue is added to or deleted from the N-  
terminus and/or the C-terminus of SEQ ID NO:6,  
wherein said homologous polypeptide has  
substantially the same physicochemical properties  
and biological activity as the polypeptide of SEQ  
ID NO:6,

(2) molecular weight

18,500  $\pm$  3,000 daltons on sodium dodecyl sulfate  
polyacrylamide gel electrophoresis (SDS-PAGE);

(3) isoelectric point (pI)

4.9 ± 1.0 on chromatofocusing;

(4) biological activity

inducing interferon- $\gamma$  production by human  
immunocompetent cells; and

(5) acute toxicity

having an LD<sub>50</sub> of at least about one mg/kg when  
tested in mice; and

(6) assay

being detected with a monoclonal antibody specific  
to the said polypeptide or said homologous  
polypeptide; and

(ii) a pharmaceutically acceptable carrier, adjuvant, excipient,  
diluent, and/or stabilizer, said pharmaceutical composition being  
~~processed and~~ administered to a subject after being processed in  
combination with or without a biologically active compound.

19(Currently amended). A pharmaceutical composition,  
comprising (i) an interferon- $\gamma$  inducing polypeptide having the  
amino acid sequence of SEQ ID NO:6, where amino acid residue 73,  
as represented by Xaa, is Ile or Thr, or a fragment thereof, and  
having the following physicochemical properties:

(1) molecular weight

18,500 ± 3,000 daltons on sodium dodecyl sulfate  
polyacrylamide gel electrophoresis (SDS-PAGE);

(2) isoelectric point (pI)

4.9 ± 1.0 on chromatofocusing;

(3) biological activity

inducing interferon- $\gamma$  production by human  
immunocompetent cells; and

(4) acute toxicity

having an LD<sub>50</sub> of at least about one mg/kg when  
tested in mice; and

(5) assay

being detected with a monoclonal antibody specific  
to the said polypeptide or said homologous  
polypeptide; and

(ii) a pharmaceutically acceptable carrier, adjuvant, excipient,  
diluent, and/or stabilizer, said pharmaceutical composition being  
~~processed and~~ administered to a subject after being processed in  
combination with or without a biologically active compound.

20(Original). The pharmaceutical composition of claim  
18, wherein said interferon- $\gamma$  inducing polypeptide is said  
homologous polypeptide.

21(Currently amended). The pharmaceutical composition  
of claim 18, ~~wherein said biologically active compound~~ which is  
used as an ~~selected from the group consisting of~~ antitumor agents  
agent, antiviral agents agent, antiseptics antiseptic,

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immunotherapeutic ~~agents~~ agent, platelet-increasing ~~agents~~ agent,  
[[and]] or leukocyte-increasing ~~agents~~ agent.

22(Original). The pharmaceutical composition of claim  
21, wherein said biologically active compound is interferon- $\alpha$ .

23(Original). The pharmaceutical composition of claim  
21, wherein said biologically active compound is interferon- $\beta$ .

24(Original). The pharmaceutical composition of claim  
21, wherein said biologically active compound is interleukin 2.

25(Original). The pharmaceutical composition of claim  
21, wherein said biologically active compound is interleukin 3.

26(Original). The pharmaceutical composition of claim  
21, wherein said biologically active compound is interleukin 12.

27(Original). The pharmaceutical composition of claim  
21, wherein said biologically active compound is TNF- $\alpha$ .

28(Original). The pharmaceutical composition of claim  
21, wherein said biologically active compound is TNF- $\beta$ .

29(Original). The pharmaceutical composition of claim  
21, wherein said biologically active compound is carboquone.

30(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is cyclophosphamide.

31(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is aclarubicin.

32(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is thiotepa.

33(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is busulfan.

34(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is ancitabine.

35(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is cytarabine.

36(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is 5-fluorouracil.

37(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is 5-fluoro-1-(tetrahydro-2-furyl) uracil.

38(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is methotrexate.

39(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is actinomycin D.

40(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is chromomycin A3.

41(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is daunorubicin.

42(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is doxorubicin.

43(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is bleomycin.

44(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is mitomycin C.

45(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is vincristine.

46(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is vinblastine.

47(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is L-asparaginase.



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48(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is radio gold colloidal.

49(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is Krestin®.

50(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is picibanil.

51(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is lentinan.

52(Original). The pharmaceutical composition of claim 21, wherein said biologically active compound is Maruyama vaccine.

Claims 53-94 (Cancelled)